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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/089,027	03/26/2002	William E. Jack	NEB-166-PUS	9409

28986 7590 09/25/2006

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EXAMINER	
HUTSON, RICHARD G	

ART UNIT	PAPER NUMBER
1652	

DATE MAILED: 09/25/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/089,027	JACK ET AL.	
	Examiner	Art Unit	
	Richard G. Hutson	1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *7/5/2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *2-4,13-22 and 27-31* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *2-4,13-22 and 27-31* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 7/5/2006 has been entered.

Applicant's amendment of claims 2-4, 13-22 and 27-31, in the paper of 7/5/2006 is acknowledged. Claims 2-4, 14-17,19-22 and 27-31 remain pending and at issue for examination.

Applicants' arguments filed on 7/5/2006, have been fully considered and are deemed to be persuasive to overcome some of the rejections previously applied. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn.

Claim Objections

Claims 13, 18 objected to because of the following informalities:

Claims 13 and 18 are dependent on rejected claims 1-3.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 2-4, 14-17,19-22 and 27-31 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The rejection is stated in the previous office action as it applied to previous claims 1-7, 11, 14-17 and 19-31. In response to this rejection applicants have amended claims 2-4, 13-22 and 27-31 and traverse the rejection as it applies to the newly amended claims.

Applicants submission that applicants have limited one of the claimed genuses of methods to those methods of use of those family B polymerases claimed in Patent US 5,500,363 according to sequence homology under specified hybridization conditions is acknowledged. Applicant's submission that applicants have limited the other of the claimed genuses of methods to those methods of use of those family B polymerases defined by an amino acid sequence identity is also acknowledged.

Applicants traverse the current rejections by traversing the previous assertions made by the examiner that the specification lacks sufficient description concerning:

(1) common structure of Family B polymerases

(2) structure-function relationship

(3) how to isolate an archaeon Family B DNA polymerase and

(4) how to test it to determine efficacy.

With respect to "common structure of Family B polymerases", applicants submit that applicants have provided detailed analysis of support in the description of the invention relating to the homogeneity of this group of enzymes(in response dated 4/14/2005).

With respect to structure-function relationships, applicants continue to submit that it is well known in protein chemistry that an enzyme has an active site that has a structure that is suited for binding a substrate in such a way to lower the energy of the reaction so as to catalyze a reaction and that the structure of the active site determines its function. Applicants submit that when a particular type of enzyme obtained from a variety of sources proves to have a conserved sequence that results in a homogeneous active site, it is reasonable to assume that this type of enzyme from different sources act in the same way. Applicants thus submit that the archaeon family B polymerase as defined by stringent DNA hybridization to defined DNA sequence is defined without ambiguity and support such by the presentation of a declaration under oath by the inventor of the strong degree of predictability of the structure-function relationship of this group of polymerases and an acyclonucleotide substrate.

With respect to "How to isolate an archaeon Family B DNA polymerase, applicants submit that applicants specification provides such guidance under the section entitled "Identifying DNA Polymerases with Similar Properties" and thus this is well within the ability of a person of ordinary skill in the art.

With respect to "How to test the DNA polymerase for efficacy", applicants submit that applicants specification provides such guidance under the section entitled "A titration assay to measure the relative efficiency of modified nucleotide incorporation" and thus this is well within the ability of a person of ordinary skill in the art.

Thus applicants submit that the above description of this assay in combination with a precise definition of the genus of Family B polymerases encompassed by the claims provide a full clear and exact description of the invention.

(5) Applicant's complete argument is acknowledged and has been carefully considered, however, continues to be found non-persuasive for the reasons previously made of record and repeated herein. Applicants argument regarding (3) how to isolate an archaeon Family B DNA polymerase and (4) how to test it to determine efficacy are acknowledged and not considered to be lacking in support of the current rejection.

While applicants argue that they adequately describe the claimed methods of use of any Family B DNA polymerase, it remains that applicants claimed genus of methods is drawn to the use of any "Archaeon Family B DNA polymerase", and this is interpreted broadly as encompassing variants and mutants of naturally occurring Archaeon Family B DNA polymerase. Given this reasonably broad interpretation, applicants have not adequately described or enabled the structural features necessary to ensure proper function to practice the claimed methods of incorporation of acyclonucleotides into fragments of DNA.

With respect to applicants arguments regarding: (1) common structure of Family B polymerases, applicants comments regarding the homogeneity shared between this

group of polymerases is acknowledged, however, such is acknowledged in light of the degree of the vast majority of DNA polymerases, many of which have a high degree of homogeneity and not all of which share the ability to incorporate acyclonucleotides into a DNA fragment. Thus applicants reasoning that the degree of homogeneity between these polymerases would or should afford certain polymerase properties is not persuasive.

With respect to applicants arguments regarding (2) structure-function relationships, and applicants submission that the archaeon family B polymerases as defined by stringent DNA hybridization to defined DNA sequence is defined without ambiguity and the support of such by the presentation of a declaration under oath by the inventor of the strong degree of predictability of the structure-function relationship of this group of polymerases and an acyclonucleotide substrate, it remains that applicants have not described the structure to function relationship for the "incorporation of acyclonucleotides into a DNA fragment". It is this structure to function relationship that would help applicants in the description and enablement of the claimed genus. Applicants pointing out of the structure to function relationship of the archaeon Family B DNA polymerases with respect to general polymerase function is acknowledged, however, not considered sufficient to describe those polymerases that have the necessary function of incorporating acyclonucleotides into a DNA fragment.

Thus for the reason previously made of record and repeated herein applicants arguments continue to be found nonpersuasive.

Applicant is referred to the revised guidelines concerning compliance with the written description requirement of U.S.C. 112, first paragraph, published in the Official Gazette and also available at www.uspto.gov.

Claims 2-4, 14-17,19-22 and 27-31 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for method for site-specific incorporation of derivatized dideoxynucleotides, acyclonucleotides or derivatized acyclonucleotides into DNA comprising reacting a archaeon Family B DNA Polymerase, a primed DNA template and a nucleotide solution containing the referred to nucleotide to produce fragments of DNA with the referred to nucleotide covalently attached to the 3'-terminal residue, wherein said archaeon Family B DNA polymerase is Vent, Deep Vent, *Pfu* and 9oNTM or the specifically disclosed variants referred to in claim 18, does not reasonably provide enablement for any method for site-specific incorporation of derivatized dideoxynucleotides, acyclonucleotides or derivatized acyclonucleotides into DNA comprising reacting any archaeon Family B DNA Polymerase, a primed DNA template and nucleotide solution containing the referred to nucleotide to produce fragments of DNA with the referred to nucleotide covalently attached to the 3'-terminal residue. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The rejection is stated in the previous office action as it applied to previous claims 1-7, 11, 14-17 and 19-31. In response to this rejection applicants have amended claims 2-4, 13-22 and 27-31 and traverse the rejection as it applies to the newly amended claims.

Applicants traverse the rejection, in combination with the above rejection based on a lack written description. This traversal is found non-persuasive for the same reasons discussed above.

Thus, applicants have not provided sufficient guidance to enable one of ordinary skill in the art to make and use the claimed invention in a manner reasonably correlated with the scope of the claims broadly including the claimed methods of use of those archaeon Family B DNA polymerase with the specified acyclonucleotide incorporation characteristic. The scope of the claims must bear a reasonable correlation with the scope of enablement (In re Fisher, 166 USPQ 19 24 (CCPA 1970)). Without sufficient guidance, determination of having the desired biological characteristics is unpredictable and the experimentation left to those skilled in the art is unnecessarily, and improperly, extensive and undue. See In re Wands 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir, 1988).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Richard G. Hutson whose telephone number is (571) 272-0930. The examiner can normally be reached on 7:30 am to 4:00 pm, M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapu Achutamurthy can be reached on (571) 272-0928. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Richard G Hutson, Ph.D.
Primary Examiner
Art Unit 1652

rgh
9/14/2006